Questions and Answers from the CTSA Technical Grant Writing Workshop December 7, 2005

I. APPLICATION

In the Format of the Application section of the CTSA RFA, there is no "Resources and Environment" section following Section F, "Biographical Sketches." Is this an oversight, or are existing resources expected to be addressed within the various components of Section G, "Institutional CTSA Program?"
Existing resources should be described within the various components of Section G, "Institutional CTSA program."

Can the 50 pages of tables be distributed throughout the document, in proximity to their respective sections?
Yes.

Where in the proposal do we include Bioinformatics - under "Biomedical Informatics" or "Design, Biostatistics, and Clinical Research Ethics?"
"Biomedical Informatics" would be a good choice.

We are describing core lab functions under "Translational Technologies and Resources" as well as under "Other program functions." Can we present all the core functions under these two areas as a single document as long as it meets the page limitation? The concern is that if we present under two different areas, it may appear rather fractured and not as unified core lab functions?
The 15-page limit on individual key functions should be observed. Applicants should determine what titles to use for the key functions they propose. An appearance of fracturing could be minimized by cross-referencing, if needed.

Once awarded, what month of the year will the non-competitive application be submitted? In what month will the new grant year begin?
NOGAs for FY2006 awards will be issued in September, 2006. The earliest possible start date would be September 30, 2006. The first budget period may be shorter than 12 months. The non-competing (type 5) application will be due two months prior to the start of the second budget period.

Will we have the opportunity to organize the document as we see fit? Or do we use traditional ABCD design for the suggested 9 sections? How long can the preamble be?
Applications must be on PHS398 forms. The number of sections (key functions) is up to the applicant, as is their ordering. All sections should be concise.

Knowing that electronic submission is being phased in for NIH grant applications, will CTSA be submitted electronically next March?
No. Electronic submission of large, complex grants is expected for June 1, 2007.

May we submit all copies of our application in 3-ring binders? May we use tabs between sections?
Please submit applications in conventional PHS398 format, using neither binders nor tabs.

What is the anticipated date for the submission of the CTSA application in FY 2007?
A submission date has not yet been determined.

Where should I place the "sharing of research resources" text within the grant application?
Follow the PHS398 instructions.

For the pilot and feasibility studies: must actual studies be submitted as part of the CTSA proposal, or must we just describe the mechanisms for soliciting and reviewing them?
The solicitation and selection processes will be the subject of review. Scientific protocols may be summarized to illustrate the type of proposal that would be selected, but they will not be reviewed for scientific merit.

Should a CTSA application and a Comprehensive Cancer Center Support grant application suggest sharing of Cores and other support research services between the two?
The applications should describe what the institution considers to be the best approach for sharing cores between the CTSA and other NIH-funded centers.

There is a section for Human Subjects in the RFA. What is to go there for the CTSA?
Follow PHS398 instructions.

May we cite literature at the end of each individual section, rather than in only one section in the application?
Yes. References may be sited at the end of the appropriate section.

Is there a Federal rule that limits us to working with just one GCRC facility at a time, or can we initiate research activities at both simultaneously?
There are no "Federal Rules" concerning the CTSA applications, merely guidelines. Multiple GCRCs should be incorporated into a CTSA application. An institution may not participate in multiple CTSA applications.

II. BUDGET

With the GCRC and K12 budgets being integrated into the CTSA, are we limited to the same direct cost vs. F&A amounts, or may these be reallocated? Could NCRR clarify the amount of indirect costs that will be available for the CTSA? Is it only 8%?
The funds currently allocated for the NCRR M01 and K12 awards and those of the RM K12, T15, and T32 awards held by the institution may be redistributed among all components of the CTSA application. Those CTSA components funded through the U54 mechanism will receive the standard institutional F&A rate. The K and T components will receive the 8% F&A rate.

Can we propose a budget for a Predoctoral T32 even if we don't have one currently?
Yes. A predoctoral T32 component allows you to develop a training pipeline for clinical researchers.

Should we provide budget justifications after each budget section (i.e., U54, K12, T32), or should we incorporate them as one after all budgets (Forms 4&5) are presented? Is there a page limit to the Budget Justification text section?
You are asked to submit 4 sets of budget pages: one each for the U54, K12, and T32 components and one summary/composite budget. Please provide the justification for each of the U54, K12, and T32 components separately—after each of these components. No specific justifications should be provided for the combined/summary budget. There is no page limit to the budget justification.

Will awards be made under separate NOGAs per budget or as one NOGA?
There will be separate NOGAs for each of the U54, K12, and T32 components.

"Rolling Up" grants NOT mandated in the RFA: The RFA states that integration of other grants and centers (in addition to the M01, etc. mandated in the RFA) will be looked upon favorably as a form of institutional commitment (e.g., Section III.2: Cost Sharing or Matching). For grants that are MANDATED to be rolled up (i.e., M01) CTSA PI must be able to re-allocate funds to other CTSA activities as needed and must have authority to shape the goals and activities of the program (within reason). One would particularly expect that funds saved through economies of scale would be put to good use elsewhere. But is this model feasible for other centers or grants funded by NIH? We are concerned that individual institutes may object if we propose "rolling up" previously awarded grants in a way that changes the budgets of those grants.
Reviewers may be favorably impressed by CTSA applications that will benefit a wide range of categorical awards supported by NIH. However, those awards will continue to be issued independently from the CTSA.

For grants covered by the Federal Demonstration Partnership (FDP):

- **a. Could we re-allocate funds into other areas of the CTSA if the grants were "rolled up?"**
- **b. Would the same apply for grants not covered by the FDP?**
- **c. Would the same apply for NIH Contracts?**
- **d. If the NIH objects to "rolling up" other grants and centers, then what does the NIH envision when it states that integration would be viewed as a positive?**

As per the previous answer, other existing grants and contracts will not be subsumed into the CTSA.

Can human subject payments or travel reimbursements be made for CTSA pilot projects?
Yes, provided that they are not coercive and have IRB approval.

A GCRC Administrator is currently funded. How many Administrators does NCRR feel are needed for the CTSA? What is the hierarchy?
Applicants should determine what best suits their needs.

Does the K30 merge with the K12 at the 5-yr renewal, or will it continue to be separately funded?
Any existing K30, NCRR K12, and RM K12s held by a successful applicant institution will be reconfigured into the CTSA, to function with a single funding cycle.

How will the current F&A rate under the M01 mechanism change under the U54 funding mechanism?
The U54 award component will reflect the institutionally negotiated F&A rate. The T32 and K12 components will receive 8% F&A.

We have a GCRC that will be folded into our CTSA proposal. In the GCRC budget there are currently patient care restricted funds, will those and other types of restricted funds be unrestricted in the budgeting toward new uses in the CTSA budget?
The CTSA NOGA will specify what funds are restricted.

In most RFAs for a 5-year project period, the funding request limit increases slightly each year from year 1 to 5. The CTSA RFA doesn't seem to do that. Will the limit be frozen at $6 million for all five years, or will applicants be allowed to account for a 3-5% increase in salary?
Annual increments and cost-of-living adjustments will follow NIH guidelines.

Can CTSA funds be used to increase IRB staffing, both professional (faculty) and clerical?
Direct CTSA costs should not be used for institutional infrastructure, such as IRBs, that are supported through F&A costs.

May funds from the T32 component of the CTSA be used to support a trainee working toward a Ph.D. in—for example—Epidemiology, Biostatistics, or Nursing?
Trainees supported through the T32 mechanism need to be working in a clinical research-related area.

May CTSA funds be used to support the purchase of equipment?
Yes. However, the need for the equipment and the costs must be justified.

The RFA notes up to $160,000 salary plus fringe as possible for a K12 scholar. Is this a new NIH cap? Does it just relate to the 75%?
The RFA K12 cap is higher than the NCRR K12 cap so as to attract more specialists and surgeons to engage in research training.

We currently support three medical student stipends for a one-year clinical research experience through our GCRC grant. Can we include medical student stipends in the U54 award?
Stipends may be included only for the Research Education T32 component.

For CTSA applications that want to take advantage of higher funding levels (and thus will include pediatric and community segments), should those segments be treated in any particular manner (e.g., as a key program with 15 pages) in the application?
Applicants are free to determine how best to integrate and describe these components.

It was mentioned that patient care costs can be requested on a per diem basis. Does NCRR anticipate nursing costs to be a part of institutional support, or can this be requested as part of the patient care budget?
Either is permitted.

Please expand on the expectation of institutional commitment. Is there any possibility that there will be a 1:1 matching requirement?
No matching is required. Institutional commitment can be shown in many ways: providing space, resources, protected time, etc. The nature and amount of the commitment will be affected by institutional circumstances.

Are K12 and K30 components supposed to be within the same budget section?
No. Current K30 activities will be supported through the U54 mechanism and should appear in the U54 budget. The K12 component is a separate budget category.

How do we determine the maximum allowed funding for year 1, given the different budget periods for our current M01 and K12 grants? Do we prorate our current awards?
Calculate the maximum allowed funding amount by adding the costs of your most recent NOGAs for all of the applicable components (such as M01, K12, etc.).

How do we consider carry forward on our current K12 in this funding request?
This funding request should not include any consideration of possible carry forward funds. This is a separate issue which will be handled on an individual basis as appropriate.

If a grantee has a current Roadmap K12, are the infrastructure costs to be kept separate or folded into the CTSA costs?
The infrastructure component of the RM K12 should remain within the K12 budget, separate from the U54 budget.

What categories are excluded from the F&A (i.e., patient care)?
Categories excluded from F&A costs are established in the institutional rate agreement.

Are all the budget page forms from PHS 398? This would include the U54, T32, and K12 and summary set.
Yes. Please use PHS398 budget pages. You are asked to submit 4 sets of budget pages: one each for the U54, K12, and T32 components and one summary/composite budget. Please provide the justification for each of the U54, K12 and T32 components separately after each of these components. No specific justifications should be provided for the combined/summary budget. There is no page limit to the budget justification.

III. CTSA STRUCTURE

The RFA states that the Director and Co-director's effort must be no less than 20%. How far down the leadership structure does this requirement apply? Is a "Co-director" someone who has broad authority over multiple aspects of the CTSA, or are directors of individual cores (e.g., a biostatistics core) also subject to the 20% minimum?
Only the PI (Program Director) and Co-Directors (if any) must devote at least 20% effort to each of their positions.

Please elaborate further on the requirements for reporting structure of the CTSA in an interdisciplinary environment where multiple schools of the institution are involved. Can this be accomplished through direct reports to someone, such as the health science center director?

The reporting requirement should provide the PI with the authority to operate and/or modify the CTSA activities of all participating schools and affiliates. The means by which this is achieved will depend on the institutional environments.

In the RFA, regarding the PI, it states that "NIH would look favorably on their participation as full-time faculty members of the Center/Department/Institute." Please clarify. Does this mean 100% effort associated with the C/D/I, with no partial effort in an academic department or in a leadership role at the institution?
The distribution of time between a C/D/I for Clinical and Translational Science and traditional academic departments will depend on institutional circumstances.

How far may we deviate from the instructions in the RFA? For example, would we be allowed to split out the Clinical Research Ethics into its own core, separate from Design and Biostatistics?
Applicants are free to propose key functions that best suit their needs. The topics listed in the RFA were for descriptive purposes and can be modified as desired.

May a CTSA award be used 50% for Implementation Science of health services research? Or, is there a limit for the split between clinical and implementation science on any percentage basis?
Applicants are free to choose the proportions of the various types of research they might undertake, bearing in mind that the intent of the RFA is to serve the infrastructure needs of a wide range of NIH Institutes.

Please explain how the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)—for space in which patients/human subjects are seen—should be applied to the CTSA's clinical facilities. In the past, it has been required of all GCRC space with a recent modification to allow for low-risk research to be conducted in non-JCAHO-certified space.
There is no requirement for JCAHO accreditation for space that will be used by a CTSA.

IV. EDUCATION, TRAINING, AND CAREER DEVELOPMENT

It appears that both the T32 and K12 are encompassed in "Research Education, Training, and Career Development," which is limited to 25 pages. Is this accurate, or are these separate/connected applications? If the former is the case, there is concern that 25 pages is too limiting.
The Research Education, Training, and Career Development section, which includes the K12 and T32 components, should be described within the 25 page limit. Tables may be used in addition.

Is it anticipated that all CTSA institutions offer M.S. & Ph.D. degrees in Clinical & Translational Research? Is it a requirement for the P20 & U54?
Higher degrees (e.g., M.S. and Ph.D.) in Clinical Research are required.

It was mentioned that the Research Education component can be used to expand training for those who do not fit eligibility criteria for current mechanisms. May trainees supported through the K12 mechanism receive specialty training at the same time?
The U54 Research Education component budget can be used for training those who do not fit current mechanisms (study coordinators, project managers, foreign nationals, etc.). Trainees supported through the K12 mechanism must hold a higher degree (e.g., M.D., D.N.P., D.D.S.) at the outset of their training and should be registered with a degree-granting program to study for a clinical research degree. They must commit a minimum of 75% of their effort to research career development; therefore, any specialty training would have to take place in the remaining 25% of available time.

In the RFA, very little was mentioned about pediatric career development, except that—if it is included—the budget can be maximum. In this case, does pediatric career development have to be separated or can the overall K12 program include a pediatric program and candidates.
Pediatric research is clearly important, and special environments or services are commonly required. Certain resources (e.g., bioinformatics, career development programs, and protocol authoring) are shared with the broad range of clinical researchers. Applicants for the maximum budget levels should indicate how the needs of pediatric researchers will be both integrated into and cared for within the framework of the whole CTSA, rather than being considered as a separate entity.

Will an M.D. plus M.S. in Clinical Research be eligible?
Yes. An M.S. in clinical research would be an appropriate higher degree to offer.

Can the CTSA be used to train masters and doctoral degree candidates?
Yes. The K12 component can train those who already have professional higher degrees, and a T32 component can support trainees for clinical research-related Ph.D.s. M.S. candidates can be supported only if they are enrolled in a combined degree program that awards the M.S. together with a professional doctoral degree.

V. GCRC-SPECIFIC QUESTIONS AND ANSWERS

Our existing GCRC has well defined collaborations with outside degree-granting institutions. As we consider transitioning to the CTSA, we would like to know what the mechanism is to continue these important collaborations within the CTSA structure.
A CTSA is free to establish collaborations that will meet the needs of its investigators.

Does the GCRC Informatics Manager move to the Bioinformatics Program? If so, is this Program responsible for managing the computer on the GCRC?

Biomedical informatics are likely to make a major contribution to a CTSA; therefore, the scale of this activity is likely to extend beyond the services currently provided by GCRCs.

Will the sample preparation lab and staff remain with the GCRC? Which key function could incorporate the biochemistry core lab?
CTSA applicants who have GCRCs are free to choose which GCRC activities to retain and which to modify, move, or eliminate. A biochemistry lab could be designated as a specialized core.

In CTSAs where multiple GCRCs from different institutions at different locations will be folded into the CTSA umbrella grant, will the different GCRCs be maintained as separate entities within the respective institutions to facilitate clinical and translational research for their patients and investigators?
The GCRC program will gradually be replaced by the CTSA program. Clinical activities that were performed within former GCRCs can continue as part of a single CTSA. Applicants for CTSAs should plan for functions that will best serve their clinical and translational science mission.

The comment was made that it was not expected that the CTSA would not cover any support for human subject protection provided by the institution. If that is true, what will be the fate of the RSA now supported under the GCRC?
Support provided through a CTSA should not take the place of an institutional compliance or enforcement office, nor should it be responsible for IRB activities. The CTSA can propose staff similar to the RSA to assist investigators in human subject safety.

What type of agreement (in writing) do we need to get from the NIH at this point, regarding a one-year extension of GCRC funds if we apply for the CTSA and are not successful the first time?
NOT-RR-06-001 stated "GCRCs with a project period end date in 2008 may request a 1-year extension of support for their M01 grant in lieu of a competing renewal application." And "NCRR will work flexibly on a case-by-case basis with GCRCs during this transition period to give them time to plan and apply for a CTSA award." If your GCRC has an end date in 2006 or 2007 and you would prefer to apply for a CTSA rather than submit a GCRC competing continuation application, then you should contact your program officer at NCRR to request this. Note that opting for a 1-year extension of the GCRC is in lieu of any future GCRC competing continuation.

VI. GOVERNANCE

What is the "Internal Steering Committee?"
An internal steering committee would be an option for internal governance. Applicants should determine what best suits their needs.

Will there be a site visit associated with the competitive submission?
No.

Please describe NIH's involvement in a U54 vs. the current M01, especially as it relates to an applicant CTSA institution and all of its sub-K's.
U mechanism grants are cooperative agreements that are often guided by Steering Committees, on which NIH has representation. The role of a Steering Committee and the NIH representatives is described in the RFA.

Will the K12 component of the CTSA be reviewed separately by a subcommittee of the CTSA review committee, or will the parent committee do the entire review?
A single committee composed of individuals knowledgeable in all relevant aspects of the applications will review the entire CTSA application.

Also, NCRR addressed the issue of the CTSA wide consortium, but the RFA sounds like the institution will need to develop a PLAN. Certainly we would enthusiastically participate, but to what extent do we need to develop a plan for that consortium?
Applicants should plan for the implementation of CTSA-wide recommendations.

Given the encouragement to involve industry, is there a conflict with the data sharing requirements of the CTSA?
The NIH Guidelines should be followed and local oversight employed.

Also, please expand on the need to develop an approach for participation in a CTSA-wide consortium/data sharing plan.
NIH will develop CTSA-wide Steering committees focusing on individual key functions. Institutions should describe how they would implement best practices (e.g., in the area of data sharing).

Will a CTSA have a Scientific Advisory Committee, and—if so—should there be a chair from medicine and pediatrics at each meeting? Will the chair positions be eligible for funding?
Applicants are free to propose a strategy and cost support to prioritize their science activities that they feel best meets their needs.

How are IRB issues handled for existing studies? If the participant clinical resources component is to have already existing clinical/translational studies, is the approach to be just an indication that there is or is not IRB approval

for these studies and, therefore, the entire grant. This would be similar to the GCRC continuation application (the schedules) with the added "wait until the award is made" if you have a grant "pending IRB" status.
No discussion of the human subjects components is required on a per protocol/study basis.

VII. PLANNING GRANTS

Should specific components (Clinical & Translational Science as a Discipline, Research Education, Training & Career Development, Research Services, Location & Organization, Senior Leadership, etc.) be addressed in the Research Plan for a P20 Planning Grant or as a supplement?
Supplements are not allowed for CTSA Planning Grant applications.

Can institutions with GCRCs retain the grant during the project period for the planning grant?
Yes. Planning awards may be held concurrently with a GCRC award.

Where should the tables be in the planning grant? Will they be part of the 25 page limit, or can they be added like an appendix? And, what are the page limits for the tables?
Tables are permitted in the planning grant and will be part of the 25-page limit. Appendices are not permitted for P20 applications.

VIII. REPORTING

Will there be an annual report?
Yes. Reportable items are summarized in the RFA and a Web-based reporting mechanism will be developed. This annual report (APR) does not replace the need to submit the yearly progress report (2590) which is the vehicle for receiving a NOGA from the NIH.

If the CTSA encourages partnerships with industry, will it be necessary to set up mechanisms to track financial support and report that support annually to NCRR?
Program Income will need to be tracked and reported annually.

The WebCAMP will be released in January for GCRCs to record research data and compile annual reports. What will be the report requirements for CTSAs, and what is the future of WebCAMP as related to the CTSA initiatives?
CTSA annual reports will be Web-based but will not use WebCAMP.

The Head of the CTSA must report to a responsible institutional official. Please expand on what constitutes a responsible institutional official. In the case of a medical school, would this be the Dean, or must it be someone with

greater authority (e.g., a Vice Chancellor or Chancellor)? Also, if an institution chooses a departmental model for the CSTA, it is hard to see how the Chair of that department would not report to the Dean of the College in which it is located. How then can the PI/Chair report to someone above the level of the Dean with trans-institutional authority?

Institutional circumstances will dictate the reporting structure. It is important that the CTSA PI have the authority to implement program adjustments as required. That is, if only one School is involved in the CTSA, its Dean would be a suitable "responsible individual." If several schools were involved, then an individual such as the Vice Chancellor would be appropriate. If more than one institution is to be part of the CTSA, then ceding of authority to the lead institution's "Responsible Individual" should be negotiated and then documented within the application.